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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/127,624	08/03/98	PONCE DE LEON	F 002076-007

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EXAMINER

WILSON, M

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

02/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/127,624

Applicant(s)

PONCE DE LEON ET AL.

Examiner

Michael Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,8 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,8 and 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Michael C. Wilson, Art Unit 1633.

Applicant's arguments filed 11-27-00, paper number 11, have been fully considered but are moot in view of the new rejections below. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5, 7, 8 and 29-40 are pending and under consideration in the instant office action.

Claim Objections

1. Claim 30 is objected to because of the following informalities: the line after "said growth factor are:" should be indented, should begin with --(i)-- and should have the "40." deleted. Appropriate correction is required.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 30 of this application. Parent application 08/905,773 (filed

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8-4-97) does not teach the amounts of the growth factors in claim 30. The effective filing date for claims 1, 4, 5, 7, 8, 29 and 31-40 is 8-4-97. The effective filing date for claim 30 is the filing date of the instant application which is 8-3-98.

Claim Rejections - 35 USC § 112

3. Claims 1, 4, 5, 7, 8 and 29-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of culturing avian PGCs comprising maintaining the avian PGCs for at least 14 days in culture comprising (i) isolating a pure population of PGCs from an avian; and (ii) culturing the pure population of PGCs in media comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs for at least 14 days in tissue culture, does not reasonably provide enablement for culturing the PGCs for at least 14 days in media comprising “growth factors in amounts sufficient to maintain said PGCs for at least 14 days” as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1, 4, 5, 7 and 8 as newly amended and claims 29-32 are directed toward a method of culturing a pure population of avian PGCs in a culture medium for at least 14 days. Claims 33-40 are directed toward a purified population of avian PGCs in culture media such that the PGCs are maintained for at least 14 days.

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The state of the art at the time of filing was that PGCs had been isolated from the heart of stage XIII and XIV chicken embryos and cultured for 5 days in the presence of 10 units/ml of LIF, 10 ng/ml bFGF, 10 ng/ml IGF and feeder cells (Chang et al., 1995, Cell Biol. International, Vol. 19, pages 143-149; page 143, col. 2, 2nd paragraph through page 144, col. 2, 2nd full paragraph). In addition, cells isolated from the blastoderm of a stage IX-XI chicken embryo were cultured for more than 160 days in the presence of 10 ng/ml bFGF, 20 ng/ml IGF, 1% vol/vol SCF, 1% vol/vol LIF and feeder cells (page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10). Simkiss of record (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) taught that the blastoderm of stage X chicken embryos contain PGCs (page 111, Fig. 4.1, top panel). Therefore, the culture of Pain comprised PGCs. The prior art of record did not teach or suggest culturing a pure population of avian PGCs in a culture medium comprising growth factors in amounts sufficient to maintain said PGCs for at least 14 days.

The specification teaches culturing a pure population of avian PGCs in a culture medium comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs for at least 14 days. Since the art does not teach the growth factors required to maintain PGCs for at least 14 days and the only method taught in the specification that results in maintaining the PGCs for at least 14 days is using LIF, bFGF, IGF and SCF, the presence of LIF, bFGF, IGF and SCF is considered essential to maintain the PGCs for at least 14 days and must be included in the claims. Therefore, claims 1, 4, 5, 7, 8, 31-35 and 37-40 require a limitation wherein LIF, bFGF, IGF and

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SCF are in the medium. Given the teachings in the art taken with the guidance provided in the specification, it would have required one of skill in the art undue experimentation to determine how to culture a pure population of PGCs for more than 14 days without LIF, bFGF, IGF and SCF.

Claims 32 and 38 are not enabled because the specification does not teach any feeder cells that provide growth factors in amounts sufficient to maintain PGCs for at least 14 days. The art at the time of filing did not teach feeder cells that produced growth factors in amounts sufficient to maintain PGCs for at least 14 days. Therefore, it would have required one of skill undue experimentation to determine how to obtain feeder cells that produce growth factors in amounts sufficient to maintain PGCs for at least 14 days as claimed.

Claims 1, 4, 5, 7, 8, 29-31, 33-37, 39 and 40 appear to be free of the prior art of record because the prior art of record did not teach or suggest culturing a pure population of avian PGCs in a culture medium comprising growth factors in amounts sufficient to maintain said PGCs for at least 14 days. Claims 32 and 38 appear to be free of the prior art because the prior art of record did not teach or suggest culturing the pure PGCs with feeder cells that produce growth factors in amounts sufficient to maintain said PGCs for at least 14 days.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 4, 5, 29-31, 33, 36, 37, 39 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 of '569 are obvious species of claims 1, 4, 5, 29-31, 33, 36, 39 and 40 in the instant application.

5. Claims 1, 7, 8, 33, 34 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (Pain et al., 1996, Development, Vol. 122, pages 2239-23348).

The claims of '569 are directed toward culturing pure PGCs for at least 14 days. The claims do not recite the limitations of maintaining the cells for at least 25 days or 4 months. However, Pain taught culturing avian embryonic cells for at least 160 days (page 2345, col. 2).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed invention in '569 to maintain the PGCs for at least 25 days or 4 months. One of ordinary skill would have been motivated to maintain the PGCs for at least 25 days or 4 months to increase the availability of the PGCs.

Conclusion

This action is non-final in view of the above rejections. No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

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